

Applicants : Jan Geliebter, George J. Christ, Arnold Melman,  
and Jamil Rehman  
Serial No. : 09/531,969  
Filing Date : March 21, 2000  
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#### REMARKS

Claims 1-36 were pending in the above-identified application. By this Amendment, applicants have amended Claims 1 and 9 to better define applicants' invention. Applicants also have cancelled Claims 6-8, 10-19, and 21-36 without prejudice, and added new Claims 37-49. The amendments to Claims 1 and 9, and new Claims 37-49, are supported by the application as originally filed, and do not introduce new material. Accordingly, entry of the amendments to Claims 1 and 9, and the addition of new Claims 37-49, are respectfully requested.

In view of the preceding amendments and the remarks which follow, applicants respectfully request that the Examiner reconsider and withdraw the rejections set forth in the June 6, 2001 Office Action, and earnestly solicit allowance of the claims currently under examination, namely, Claims 1-5, 9, 20, and 37-49.

#### 35 U.S.C. §112, 1<sup>st</sup> Paragraph Rejection

Claims 1-8, 10-18, and 20 were rejected under 35 U.S.C. §112, first paragraph. In addition, Claims 1-20 and 28-36 were rejected under 35 U.S.C. §112, first paragraph. Applicants herein have cancelled Claims 6-8, 10-19, and 21-36 without prejudice, and amended Claim 1 to recite a method of regulating smooth muscle tone in a subject, by the introduction and expression of a DNA sequence encoding a potassium channel protein in a sufficient number of smooth muscle cells of the subject to regulate smooth muscle tone in the subject. Applicants submit that the invention as claimed is enabled by the specification as filed.

In particular, the specification as filed provides evidence that a DNA sequence encoding a potassium channel protein, either maxi-K or  $K_{ATP}$ , can regulate smooth muscle tone, either in penis or in bladder (*see, e.g.*, page 72, line 1, through to

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page 73, line 18). Applicants submit that, based upon these results, the skilled artisan would have a reasonable expectation that a DNA sequence encoding other potassium channel proteins would have a similar regulatory effect in other types of smooth muscle. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

#### 35 U.S.C. §112, 2<sup>nd</sup> Paragraph Rejection

Claims 7-19, 21-27, and 30-34 were rejected under 35 U.S.C. §112, second paragraph. Applicants have cancelled Claims 6-8, 10-19, and 21-36 without prejudice, and this rejection should now be moot. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

#### 35 U.S.C. §102 Rejections

Claims 21-25, 27-33, and 35-36 were rejected under 35 U.S.C. §102(e) as being anticipated by Kaczorowski (1998). In addition, Claims 21-23, 27-31, and 35-36 were rejected under 35 U.S.C. §102(e) as being anticipated by Kalecko *et al.* (2000). Finally, Claims 21, 25-27, 28, and 33-34 were rejected under 35 U.S.C. §102(b) as being anticipated by Yoshitaka *et al.* (1993). Applicants have cancelled Claims 21-36 without prejudice, and the rejections under 35 U.S.C. §102(b) and (e) should now be moot. Accordingly, reconsideration and withdrawal of these rejections is respectfully requested.

#### Double Patenting

Claims 1-15, 17-18, and 20 of the present application were rejected under the doctrine of obviousness-type double patenting, as being unpatentable over Claims 1-9 of U.S. Patent No. 6,150,338. Claims 1-15 of the subject application were also rejected under the doctrine of obviousness-type double patenting, as being unpatentable over Claims 1-2 of U.S. Patent No. 6,239,177.

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In response to these rejections, applicants file herewith a terminal disclaimer, limiting the term of the subject patent, if issued, to the terms of U.S. Patent Nos. 6,150,338 and 6,239,177. In this regard, applicants note that the subject application and Patents No. 6,150,338 and 6,239,177 are commonly owned. A check is enclosed to cover the \$55.00 fee for filing a Terminal Disclaimer. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

No fee, other than the \$200.00 fee for a two-month extension of time and the \$55.00 fee for filing a Terminal Disclaimer, both for a small entity, is deemed necessary in connection with the filing of this Amendment. If any fee is required to preserve the pendency of the application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785.

Respectfully submitted,

AMSTER, ROTHSTEIN & EBENSTEIN  
Attorneys for Applicants  
90 Park Avenue  
New York, New York 10016  
(212) 697-5995

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New York, New York

By:   
Craig J. Arnold  
Reg. No. 34,287



96700/596

SCHEDULE A

REDLINED VERSION

In the Claims:

Please rewrite Claims 1 and 9 as follows:

1. (amended) A method of regulating smooth muscle tone in a subject, comprising the introduction and expression of a DNA sequence encoding a potassium channel protein ~~a potassium channel protein involved in the regulation of smooth muscle tone~~ in a sufficient number of smooth muscle cells of the subject to regulate smooth muscle tone in the subject.

9. (amended) The method of Claim 1 8, wherein the potassium channel protein is maxi-K or K<sub>ATP</sub>.

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